IV. Issues for Discussion

We are specifically interested in hearing comments regarding the following questions and any other pertinent information related to the feasibility of the electronic submission of premarket applications and other regulatory information related to the review of human drug applications including postmarket data sources:

1. What would help improve the quality of electronic submissions to the agency?
2. What would help increase the quantity of electronic submissions to the agency?
3. How would you prioritize these quality and quantity improvements?
4. What data standards are needed to implement these improvements?
5. How should FDA engage stakeholders while developing, testing, and implementing these solutions?
6. What topics are most useful to include in IT plans?
7. What lead time is needed for stakeholders to respond to and be in alignment with FDA initiatives?
8. How should FDA coordinate with stakeholders on the adoption and implementation of data standards?
9. What data standards areas provide the greatest challenge?
10. What approaches will facilitate the most effective and efficient adoption and implementation of data standards?
11. What key areas require new or expanded electronic submissions guidance?
12. What lessons learned and best practices should FDA consider as we transition from program-specific to enterprise IT solutions using a reusable and modular model?
13. What specific concerns (i.e., security, confidentiality, etc.) exist for a third party entity or entities providing services related to electronic submissions and review and how can they be addressed?

V. Notice of Public Meeting

The Commissioner of Food and Drugs is announcing that the public meeting will be conducted by FDA senior management. Persons who wish to participate in the meeting must file a written or electronic notice of participation with the Division of Dockets Management (see **ADDRESSES** and **DATES**). No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

VI. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic notices of participation and comments for consideration. To permit time for all interested persons to submit data, information, or views on this subject, the administrative record of the meeting will remain open until 2 weeks prior to the public meeting. Persons who wish to provide additional materials for consideration should file these materials with the Division of Dockets Management (see **ADDRESSES**). You should annotate and organize your comments to identify the specific questions to which they refer (see section IV of this document). Two paper copies of any mailed comments are to be submitted, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VII. Transcripts

The meeting will be transcribed. Transcripts of the meeting will be available for review at the Division of Dockets Management (see **ADDRESSES**) and on the Internet at *http://www.fda.gov/ohrms/dockets* approximately 21 days after the meeting. You may place orders for copies of the transcript through the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, Rm. 6–30, Rockville, MD 20857, at a cost of 10 cents per page.

Dated: September 17, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 07–4692 Filed 9–18–07; 12:12 pm]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Research Resources Special Emphasis Panel, Florida International University Site Visit.

Date: October 18–19, 2007.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Park Plaza Hotel, 415 North Monroe Street, Tallahassee, FL 32301.

Contact Person: Guo Zhang, PhD, MD, Scientific Review Administrator, National Center for Research Resources, or National Institutes of Health, 6701 Democracy Boulevard, 1 Democracy Plaza, Room 1064, MSC 4874, Bethesda, MD 20892–4874, 301–435–0812, *zhanggu@mail.nih.gov.*

Name of Committee: National Center for Research Resources Special Emphasis Panel, Tulane NPRC.

Date: October 29–31, 2007.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Wyndham New Orleans, 100 Rue Iberville, New Orleans, LA 70130.

Contact Person: Carol Lambert, PhD, Scientific Review Administrator, Office of Review, National Center for Research Resources, National Institutes of Health, 6701 Democracy Blvd., 1 Dem. Plaza, Room 1076, Bethesda, MD 20892, 301–435–0814, *lambert@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.371, Biomedical Technology; 93.389, Research Infrastructure, 93.306, 93.333, National Institutes of Health, HHS)

Dated: September 14, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–4669 Filed 9–20–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice